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Report Highlights:

Ecuador maintains a number of anti-biotech laws and regulations but there is no enforcement and trade in corn and soybean products continues. However, this situation can change quickly and efforts are needed to strengthen the institutional capacities to establish and enforcement regulations based on sound science and international standards.

Includes PSD Changes: No
Includes Trade Matrix: No
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SECTION I. EXECUTIVE SUMMARY

Ecuador has a number of laws and regulations that could impact the importation, distribution and use of products derived from biotechnology but it lacks a specific law that directly regulates biotechnology. In April 2006, Ecuador enacted the Food and Nutrition Security law that invokes the precautionary principle and calls for prohibitions to use, handle, trade or import any food products that are or contain GMOs. The regulation initially created trade problems with soybean meal and soybean oil imports but backlash from the industries that use these products as inputs lead the government to drop any enforcement measures. As Ecuador imports almost 60 percent of its corn demand, 99 percent of cotton, and 90 percent of soybean meal and oil, these products have been entering with no restrictions or review.

Ecuador ratified the Cartagena Protocol on Biosafety in November 2002, and its general policies on Biosafety are expressed in several existing laws, including the Constitution. Article 89 of Ecuador's Constitution mandates that the Government will take all measures to "regulate, under strict biosafety standards, the propagation, research, use, trade, and importation of genetically modified organisms".

Currently, Ecuador's Constitutional Assembly and the Executive have conflicting views in regards to GMO's. A majority of the assembly supports anti-GMO position, while the President defends the use of biotechnology for agriculture and medical applications.

SECTION II. BIOTECHNOLOGY TRADE AND PRODUCTION

According to the Ecuadorian Institute for Agricultural Research (INIAP), given the incipient technology and infrastructure available, Ecuador does not have the capacity to conduct any GMO-related research; therefore it does not commercially produce any biotechnology crops. However, INIAP conducts genetic research to improve the quality of seeds through hybrids for cocoa, potatoes, tomato, corn, rice and soybeans.

Furthermore, given the nonexistence of specific biotechnology legislation, Ecuador does not allow importation of seeds containing GMOs. According to the Ministry of Agriculture, all seeds used for corn, soybean and other plantations are either hybrids developed by the INIAP or other certified imported seeds that do not contain GMOs, and which have passed through a rigorous in-country certification process.

A growing proportion of the supply of corn, cotton, soybean meal, and soybean oil for industrial use is of foreign origin. A brief description of the commercial situation of these products follows:

- Presently, Ecuador imports 60 percent of its corn demand. Imports reached 552,000 MT in 2007, 98 percent of which originated in the United States and the remaining from Argentina and Uruguay.
- Ecuador purchases 99 percent of its cotton needs from the United States, reaching 14,000 MT in 2007.
- Soybean meal and oil imports are also rising with Argentina and Uruguay as main suppliers. However, depending on prices, in some years, Ecuador purchases important volumes of soybean meal from the United States. Overall imports in 2007 reached 400,000 MT for soybean meal and 114,000 MT of oil.

SECTION III. BIOTECHNOLOGY POLICY

Regulatory Framework

According to the Environmental Management Law, the Ministry of Environment of Ecuador is the entity in charge of regulating the production, propagation, research, use, trade and importation of genetically modified organisms (GMOs). The same law under article 8 establishes the coordination authority of the Ministry of Environment over the decentralized Environmental Management System, and allows for other institutions, such as the Ministries of Agriculture, Health and Foreign Trade to have direct authority over their own relevant issues.

Although the institutions are in place, there is no specific law or regulation on biotechnology and biosafety. The environmental management law is very broad and does not deal with specific issues of agricultural biotechnology and biosafety. However, a broad national policy on biosafety is clearly expressed in existing laws. The Constitution, for example, promotes a series of guidelines regarding biotechnology; such as the right of Ecuador's people to "live in a safe and balanced environment" (article 23), the government's obligation to promote public debate regarding decisions that may affect the environment (art. 88), the precautionary principle (art. 91), the strict regulation of biosafety (art. 89), and the protection of consumers rights (art. 92).

Other national laws such as the Health Code, the Consumer Rights Protection Law, the Agricultural Development Law, the Law of Seeds, and the Plant and Animal Health Law are of general applicability but do not provide specific guidance on biosafety issues.

On the international front, as a signatory of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety, Ecuador is obliged to issue policies and regulations in accordance with the precepts of these international agreements. Also, as a member of the Andean Community of Nations, Ecuador is subject to Andean Decision 523, which states an Andean Strategy on Biodiversity that must be taken into account by all members in issuing their regulations on biosafety.

Until April 2005, there was a proposed text for a "Law of Conservation and Sustainable Management of the Biodiversity" (Biodiversity Law) that would have served as a framework for Ecuador's regulations on biosafety and biotechnology. The text aimed at providing technical standards and a comprehensive regulatory system that would have ensured proper control of products derived from biotechnology and would not unjustifiably block trade.

This proposed bill was first submitted to Congress in April of 2002 and later debated without consensus. A second debate was scheduled for February of 2003, but it never happened. This time, political parties controlled by indigenous, environmentalists and leftist groups in the Ecuadorian congress used filibusters to delay a decision. Finally, the proposal was filed away and these groups counter-attacked by adding two articles to a controversial Food and Nutrition Security bill that bans any production, use, import or trade of biotech foods in Ecuador.

Specific Laws dealing with Biosafety and Biotechnology

Labeling: The Law for Protection of Consumer's Rights

This law, enacted on July 10 of 2000, regulates the supplier-consumer relations by promoting knowledge and protection of consumer's rights. It has a clause by which ambiguous dispositions should be interpreted to favor the consumer. The public entity in charge of

enforcing this law is the Office of the Ombudsman. However, little or nothing has been done to exercise such enforcement.

On regards to Biotechnology, article 13 of this law states clearly that " in case that products sold for human or animal consumption had been produced using biotechnology or any type of genetic manipulation, labels must warn of this fact using highlighted characters". Despite this specific regulation, there are no products in the Ecuadorian market, whether imported or locally produced, that contain such warning. Article 14, furthers the explanation of labeling by declaring minimum labeling requirements for food, which should include the biotech process.

As to health and safety, this law has a supplemental character by leaving room for specific laws dealing with health protection matters to regulate specific issues. However, the non-existence of a law on biosafety and biotechnology provides that this law is currently the only one in place dealing specifically with biotechnology labeling.

An inter-institutional working group that includes Ecuador's Standardization Institute and the Ministry of Health was formed to prepare new standards for food labeling. The proposed text has been waiting for over a year to be submitted to the WTO for comment. Based on the provision of article 13 of the Consumer Rights law, this proposed standard would sets a requirement for biotech foods to be labeled as to contain GMOs, and for foods containing GMO ingredients to declare the percentage of such GMOs in their composition.

Imports of Vegetable Materials and Animals: Laws of Animal and Vegetable Health

Article 4 of the Vegetable Health law establishes that any import of vegetable materials for propagation, including those used for research must obtain a previous authorization from the Ministry of Agriculture. In the case of animals used for genetic improvement, the Animal Health law provides requirements and authorizations from the Ministry of Agriculture, and establishes the obligation to comply with Andean regulations.

Authorized Biotech Foods: Rules for Sanitary Registration and Control

This regulation deals with the sanitary registration of national and imported food and beverage products for human consumption in Ecuador. Article 50 of this regulation makes reference to fines and penalties, which will be applied according to the dispositions of the Consumers Rights Protection law.

Furthermore, article 54 mentions that biotech and/or GMO foods will only be authorized to enter Ecuador when such products comply with the requirements of the Ministry of Health, which would issue a positive list of transgenic products authorized for import. Such a list does not exist, and it is unlikely that it will be issued in the future.

Food and Nutrition Security Law

The main objective of this law is to promote and provide access for the population of Ecuador to food and nutrition. It declares food security as a primary national policy and creates the "National System for Food Security and Nutrition" under the Ministry of Health. The law is based on Constitutional principles such as people's rights to quality of life through food and nutrition, and to health through protection and promotion of food security (articles 23 and 42 of Ecuador's Constitution). Also, it considers the Declaration of Human Rights, the

International Covenant on Economic, Social and Cultural Rights, and others (excluding the Cartagena Protocol) as the foundations for the principles of the law.

The Food and Nutrition Security bill is not a technical law and limits its ruling to social participation, sustainability food sovereignty and others. The National System for Food Security and Nutrition is managed by the National Food Security Council (NFSC), which is created under the umbrella of the Ministry of Health, and is presided by the Minister of Health. There is no mentioning or participation of the Ministry of Environment (the authority on biosafety according to Ecuador's Environmental Management Law) in the NFSC. It rather includes members from rural and provincial representations usually controlled by indigenous groups that continue uphold negative views on biotechnology.

Article 21 represents the most controversial part of this law. Literal D under article 21 prohibits production, use, storage, imports and marketing of foods for human consumption that are or contain GMOs until technical studies demonstrate their safety for human consumption and the environment. The National Agricultural Research Institute (INIAP) and the Agricultural Safety Service (SESA), both dependencies of the Ministry of Agriculture, shall carry out such technical studies depending on the type of product. However, neither INIAP nor SESA have the technical capacity or economic resources to carry out this research. Furthermore, literal E of article 21 prohibits that Ecuador receives or uses products that are or contain GMOs in the social food aid programs. Again, such prohibition stands until technical studies confirm that the products are safe for human consumption and the environment.

A final article states that this law shall prevail over other laws that may oppose its ruling. This means that in case a specific and technical biosafety law were enacted; the provisions under the Food and Nutrition Security law would prevail.

This clearly represents a trade barrier for any commodities imported into Ecuador that may contain GMOs. In fact, soon after its issuing in May 2005, the Ministry of Agriculture of Ecuador stopped for three weeks imports of soybean meal and soybean oil. This caused great difficulties to the poultry, animal feed, cooking oil and tuna canning industries.

Even though the provisions of this law were initially enforced, a technical error found in the text gave Ecuador's Attorney General enough reason to declare this bill as unenforceable. To date, the law has not been revised and there have not been reports of shipments being stopped or import permits being denied as a result of this regulation.

The Health Code

As a continuation of the anti-biotechnology policy, Ecuador's Congress passed a new Health Code law in December 2006. This is a general law dealing with the protection of human health, and includes provision on matters of food safety. This bill literally reintroduced the provisions of the Food and Nutrition Security law and corrected its technical errors. However, it does not resolve the issue of Ecuador's lack of capacity to determine the safety of food products derived from biotechnology. The law also leaves the implementation of its biotechnology-related dispositions to the application rules that are still to be issued.

The Ministry of Health of Ecuador has the lead in writing draft application rules for this law, which cannot be fully enforced without them. For this reason, imports of food products continued normally, and the Ministry of Agriculture has not issued a position on the matter.

Application rules are not likely to be available anytime soon. Affected private sector industries plan to work with Ecuadorian authorities to develop implementing regulations that would not impede trade in products derived from biotechnology.

SECTION IV. MARKETING ISSUES

The use of biotechnology in food is a new and intricate topic for discussion in Ecuador. The majority of consumers are not aware of the existence of food products derived from the use of biotechnology, and in a country with great food insecurity like Ecuador, this may not be an issue of major concern to the poor and struggling majority. However, environmental and indigenous groups are fully aware of the issue, and although they lack scientific evidence of the implications of biotechnology, they have been successful in keeping any biotech-related products from entering Ecuador as a requirement to preserve this country's mega-biodiversity. In addition, continued application of the Precautionary Principle in Ecuador is likely to create further trade controversies, as is happening with the Food and Nutrition Security law.

There is no specific information related to the market acceptance of biotech foods. However, our perspective is that if biotech products are required special labels "alerting" of presumable harmful characteristics, the majority of Ecuadorian consumers will certainly reject them.

Another concern arises when Ecuador currently purchases – basically from the United States and Argentina – 99 percent of its corn imports, along with 99 and 90 percent of its cotton and soybean meal needs respectively without any specific biotechnology requirements. The animal feed as well as the poultry, pork, cooking oil, tuna canning and snacks industries currently use these products in their formulations, and it is unlikely that Ecuador would have the capacity to supply this demand in the near future. Therefore, the latest issuance of restrictive rules not only hurts U.S. export interests, but also complicates the survival of these local industries and jeopardizes Ecuador's food security.

In addition, Ecuador does not have either the resources or the scientific capacity to conduct high-level research on agricultural biotechnology, so it must rely on foreign technologies and research results. Ecuador is also incapable of submitting enough scientific evidence about the possible risks of the use of biotechnology as a way to justify restrictive trade measures against biotech foods. However, it is clear that Ecuadorian authorities are worried about the issue of "dependence" from foreign technologies and imports of certain products, such as planting seeds and oilseeds. There is also an increased fear from farmers that allowing biotech seeds will hurt their plantations, and that using these products will turn their production capacity into a dependency relationship with multinational corporations.

Even with the lack of accurate information about biotechnology among consumers and policymakers in Ecuador, few activities related to biotech capacity building and outreach have been carried out by government institutions. However, the U.S. Agricultural Affairs Office in Quito has been active in the past few years on issues related towards promoting biotechnology and agricultural research. In November of 2001, post organized an EMO-funded conference on Agricultural Biotechnology presented by U.S. scientists and experts, and which was directed towards local government officials involved in biotechnology and environmental issues on agriculture. Post has also made use of Cochran resources to have policy makers, key players and journalists participate in short training courses on biotechnology issues in Hawaii and Michigan. Further efforts are being made to continue with this type of assistance by using USDA's food aid programs to improve Ecuador's trade capacity by providing funds for international agricultural training and in-country research.